Application No.: 10/609,233

Amendment Dated December 19, 2007 Reply to Office action of July 19, 2007

Amendments to the Claims:

- 1. (Currently Amended) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising about 0.1 mg/ml to about 15 mg/ml of a hypertension reducing agent, wherein said formulation is suitable for local administration to the lungs of a mammal such that a systemic effect is circumvented and said pulmonary hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator and wherein said formulation is suitable for administration via inhalation to a mammal in need thereof, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.
- (Currently Amended) The formulation of claim 1, wherein said formulation is suitable for <u>local</u> administration to the <u>lungs of a mammal by oral inhalation</u> via nebulization.
 - 3-4. (Canceled)
- (Original) The formulation of claim 2 comprising about 1 mg/ml to about 10 mg/ml of said pulmonary hypertension reducing agent.
 - 6-11. (Canceled)
- (Original) The formulation of claim 2, wherein said formulation is an aqueous suspension.
 - 13. (Original) The formulation of claim 12, wherein said suspension is sterile.
- (Original) The formulation of claim 13, wherein said suspension comprises an emulsifier.
- (Previously Presented) The formulation of claim 14, further comprising at least one complexing agent including sodium edetate.

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(Original) The formulation of claim 2, wherein said formulation comprises a
preservative.

17-20. (Canceled)

 (Original) The formulation of claim 2, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

22-24. (Canceled)

- (Original) The formulation of claim 2, wherein said formulation is suitable for treating primary pulmonary hypertension.
- (Original) The formulation of claim 2, wherein said formulation is suitable for treating secondary pulmonary hypertension.
- 27. (Currently Amended) A method of treating pulmonary hypertension in a mammal, said method comprising the step of <u>locally</u> administering to <u>the lungs of said mammal</u> a formulation comprising about 0.15 mg/ml to about 15 mg/ml of a hypertension reducing agent <u>such that a systemic effect is circumvented</u> and at least one complexing agent, wherein said hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator, and wherein said formulation is suitable for administration via inhalation, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.
- (Currently Amended) The method of claim 27, wherein said formulation is locally administered to the lungs of said mammal by oral inhalation via nebulization to said mammal.

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- (Original) The method of claim 28, wherein said formulation is administered via jet nebulizer, ultrasonic nebulizer or breath-actuated nebulizer to said mammal.
- (Original) The method of claim 27, wherein said formulation is premeasured, premixed and prepackaged.
 - (Canceled)
 - 32. (Original) The method of claim 31, wherein said formulation is sterile and stable.
 - (Canceled)
- (Original) The method of claim 27, said method further comprising the step of administering to said mammal an inotropic agent.

35-37. (Canceled)

- 38. (Currently Amended) A kit for treating pulmonary hypertension in a mammal, said kit comprising an prepackaged formulation comprising about 0.1 mg/ml to about 15 mg/ml of a hypertension reducing agent and at least one complexing agent, wherein said formulation is suitable for local administration to the lungs of a mammal such that a systemic effect is circumvented and said hypertension reducing agent is at least one of an ACEI, ARB, betablocker, calcium-channel blocker or vasodilator, and wherein said formulation is suitable for administration via nebulization to a mammal in need thereof, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.
 - (Original) The kit of claim 38, wherein said formulation is prepackaged.
- (Original) The kit of claim 38, further comprising instructions relating to said formulation.

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41-50. (Canceled)

- 51. (Currently Amended) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising an aqueous suspension having about 0.1 mg/ml to about 15 mg/ml of a calcium-channel blocker and at least one complexing agent selected from the group consisting of ethylenediaminetertraacetic acid, citric acid, nitrilotriacetic acid, sodium edetate and salts thereof; wherein said formulation is suitable for local administration to the lungs of a mammal such that a systemic effect is circumvented and said formulation is suitable for administration via inhalation to a mammal in need thereof, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.
- 52. (Previously Presented) The inhalable formulation according to claim 51, wherein said calcium-channel blocker includes at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.
- 53. (Previously Presented) The inhalable formulation according to claim 51, wherein the formulation comprises from about .001 to 10 mg/ml of said calcium-channel blocker and from about 0.01% to 90% of a suspending agent.
- (Previously Presented) The inhalable formulation according to claim 53, wherein said suspending agent comprises water, alcohol, glycol, aqueous saline solution, and combinations thereof.
- (Previously Presented) The inhalable formulation according to claim 52, comprising from about 0.01 mg/ml to 10 mg/ml of said calcium-channel blocker.
 - (Canceled)

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- (Previously Presented) The inhalable formulation according to claim 51, wherein said formulation is premeasured, premixed and prepackaged.
- 58. (Previously Presented) The inhalable formulation according to claim 51, wherein said suspension includes at least one buffer selected from the group consisting of sodium hydroxide, sodium citrate and citric acid.
- 59. (Previously Presented) The inhalable formulation according to claim 51, wherein said formulations is disposed in a dispensing container that is configured to deliver said formulation via nebulization.
- 60. (Previously Presented) The inhalable formulation according to claim 59, wherein said dispensing container is capable of delivering a single unit dose of a therapeutically effective amount of said calcium-channel blocker.
- 61. (Previously Presented) The method of claim 27, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.
- 62. (Previously Presented) The method of claim 27, wherein said formulation comprises from about 0.001 to 10 mg/ml of said calcium-channel blocker and from about 0.01% to 90% of a suspending agent.
- 63. (Previously Presented) The method of claim 62, wherein said suspending agent comprises water, alcohol, glycol, aqueous saline solution, and combinations thereof.
- (Previously Presented) The method of claim 62, wherein said formulation comprises from about 0.01 mg/ml to 10 mg/ml of said calcium-channel blocker.
 - 65. (Canceled)

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- 66. (Previously Presented) The kit of claim 38, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.
- 67. (Previously Presented) The kit of claim 38, wherein said formulation is prepackaged in a dispensing container that is configured to deliver a single unit dose of a therapeutically effective amount of said calcium-channel blocker via nebulization.
- 68. (Previously Presented) The kit of claim 67, wherein said dispensing container is prefilled with about 0.1 to 5.0 ml of said formulation.
- (Previously Presented) The kit of claim 67, wherein said formulation is administered via jet nebulizer, ultrasonic nebulizer or breath-actuated nebulizer to said mammal.